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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,969	03/21/2000	Jan Geliebter	96700/596	6902

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/531,969	GELIEBTER ET AL.	
	Examiner	Art Unit	
	Robert M Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54,58 and 59* is/are rejected.

7)☒ Claim(s) *55-57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 June 2004 has been entered.

In addition, Applicant's request to enter and consider the submissions made on 27 April 2004 is granted and such submissions are entered for consideration.

No Claim has been cancelled, amended, or added.

Claims 50-59 are presently pending and considered.

Examiner Reassignment

The Examiner for this Application has changed. Applicant should note that the newly assigned Examiner is Robert M. Kelly; however, the Art Unit and Technology Center for this Application has not changed.

Information Disclosure Statement

The Information Disclosure Statement filed by Applicant on 8 July 2004 has been considered, and a copy of the initialed and signed Information Disclosure Statement is enclosed with this Official Action; however, two cited abstracts, i.e., XP002120829 and XP002282785 have not been provided with a proper citation that one of skill in art could use to obtain a copy of these abstracts himself/herself. Consequently, these references could not be listed on any patent

that may issue from the instant Application. Therefore, although considered and reviewed by the Examiner, they have been crossed-out to indicate that these references should not be so-listed on any patent that may issue from the instant Application. If Applicant desires these abstracts to be listed on any patent that may issue from the instant Application, Applicant is invited to provide a proper citation of the subject abstracts.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-54 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although maintained for reasons of record, the rejection is restated to help Applicant understand the rejection.

The invention of Claims 50-54 and 58-59 encompass:

(i) any potassium channel protein that enhances relaxation of penile smooth muscle (Claims 50 and 59);

(ii) any calcium sensitive potassium channel protein that enhances relaxation of penile smooth muscle (Claim 51);

(iii) any metabolically gated potassium channel protein that enhances relaxation of penile smooth muscle (Claim 52); and

(iv) any inward rectifier potassium channel protein that enhances relaxation of penile smooth muscle (Claim 53).

These agents of these claims are broad in scope, being defined on the basis of their effect, and not on any specific structure. The specification broadly discloses, respectively:

(i) genes for more than thirty potassium channels have been identified; however, only two are present and/or physiologically relevant to corporal smooth muscle: K-ATP, and maxi-K (SPECIFICATION, pp. 27-28, paragraph bridging);

(ii) the maxi-K channel (SPECIFICATION, p. 27, paragraph 1);

(iii) the six Kir families (SPECIFICATION, p. 28, paragraph 2); and

(iv) the six Kir families (SPECIFICATION, p. 28, paragraph 2).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, while a number of calcium channels have been discussed, the requisite core structure from which to discern the various members of the various genera cannot be discerned from the disclosure given. Moreover, because the specification states that "Despite the plethora of known [potassium-channel] subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated [potassium] channel (i.e., [K-ATP]), and (2) the large-conductance, calcium sensitive [potassium] channel (i.e., the [K-Ca] or maxi-K channel) ...." (SPECIFICATION, p. 27, paragraph 2). The specification does not provide any disclosure as to

what would have been the required structure which would allow one to distinguish the various species of the genera. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e., other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other characteristics are that the potassium channel enhances relaxation of penile smooth muscle, and may further be calcium sensitive (SPECIFICATION, p. 27, paragraph 1), metabolically-gated (SPECIFICATION, p. 28, paragraph 2), or inward-rectifying (Id.).

Such functional characteristics, however, do not allow one of skill in the art to distinguish the different members of the genera from each other.

Applicant's attention is directed to *In re Shokal*, 113 USPQ 283 (CCPA 1957), wherein it is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; *In re Wahlforss*, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of any potassium channel protein that enhances relaxation of penile smooth muscle, any calcium-sensitive potassium channel protein that enhances relaxation of penile smooth muscle, any metabolically-gated potassium channel

protein that enhances relaxation of penile smooth muscle, or any inward-rectifying potassium channel protein that enhances the relaxation of penile smooth muscle, at the time the application was filed; such is true particularly in view of the fact that no other proteins than maxi-K or K-ATP were known to have any physiological relevance to penile smooth muscle cells, and Applicant provided no other examples of new potassium channels that would enhance the relaxation of penile smooth muscle cells. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Response to Argument – written description, old rejections

Applicant's argument and declaration submitted 27 April 2004 have been fully considered but are not found persuasive.

Applicant argues that the meaning of the sentence spanning pages 27-28 of the specification was meant to characterize the state of the art, and more specifically, the physiological import of endogenous maxi-K and K-ATP; however, such sentence was not meant to limit the invention, which relies on the use of nucleic acid[s] encoding exogenous potassium channels. The maxi-K and K-ATP are provided again in the Application as examples of exogenous potassium channels that can be used to regulate corporal smooth muscle tone. (Applicant's argument of 27 April 2004, p. 2, paragraph 3 (utilizing quotations from the declaration of Dr. Christ and Dr. Melman)).

Applicant's argument is not persuasive. In essence, Applicant appears to be arguing that they envisioned the use of many types of potassium channels, even though maxi-K and K-ATP were the only potassium channel proteins known at the time to have any physiological importance to such cells. However, merely envisioning any particular protein that provides a

desired function is not what is required for written description. Satisfaction of this requirement may be made by an actual or constructive reduction to practice. Applicant has not actually reduced all members of each genera to practice; however, by constructive reduction to practice, Applicant may address each of the genera. Constructive reduction to practice would be providing such information required, based on scientific principle, that the various members of the genera would provide the desired outcome. Such is the reason for the above-given reanalysis of the various genera: an understanding of a core structure from the known members of the genera, coupled with the function, would provide the Artisan with the ability to reasonably predict that each of the members of the genera are met. However, Applicant's two proteins known at the time of filing to be physiologically relevant to the desired effect are not enough to determine such core structure and correlate it to any particular genera. Such has been stated throughout the previous rejections (e.g., Official Action of 30 January 2004, p. 3, paragraph 3-p. 4, paragraph 1). Hence, it is maintained that Applicant may have conceived of such genera, but such conception does not correspond to constructively reducing the various genera to practice, and the written description requirement has not been met for reasons of record.

Claim Rejections - 35 USC § 112 – Enablement, old

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50-54 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods to the extent of nucleotide sequences

encoding potassium channel proteins that are K-ATP or maxi-K, does not reasonably provide enablement for all other methods embraced by the claims for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Response to Arguments – Enablement, old

Applicant's arguments and declaration co-submitted on 27 April 2004 have been fully considered but are not found persuasive.

Applicant's argument and declaration, although addressed to both written description and enablement, appear to be more appropriate to written description, as questions as to what genera the inventors considered themselves in possession of are addressed (See Supra, Response to Arguments – written description, pp. 6-7), (Applicant's response of 27 April 2004, pp. 2-3).

Such argument is not found persuasive for reasons of record. Applicant specifically stated in the specification that "Despite the plethora of known [potassium-channel] subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated [potassium] channel (i.e., [K-ATP]), and (2) the large-conductance, calcium sensitive [potassium] channel (i.e., the [K-Ca] or maxi-K channel) ...." (SPECIFICATION, p. 27, paragraph 2). As such, the Artisan could not reasonably predict that any other potassium channel would be efficacious in the presently claimed methods (e.g., Official Action of 30 January 2004, p. 5, paragraph 1).

Allowable Subject Matter

Claims 55-57 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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